

## Environmental Protection Agency

## § 155.52

(c)(2)(D) apply to the submission, compensation, and exemption of data required to conduct a registration review.

### **§ 155.50 Initiate a pesticide's registration review.**

The Agency will initiate a pesticide's registration review by establishing a docket for each registration review case, except for cases covered under § 155.46, and opening it for public review.

(a) *Contents of the registration review case docket.* The Agency will place in this docket information that will assist the public in understanding the types of information and issues that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

(1) An overview of registration review case status;

(2) A list of current registrations and registrants, any FEDERAL REGISTER notices regarding pending registration actions, and current or pending tolerances;

(3) Risk assessment documents;

(4) Bibliographies concerning current registrations;

(5) Summaries of incident data; and

(6) Any other pertinent data or information.

(b) *Public review of the registration review case docket.* The Agency will publish a notice in the FEDERAL REGISTER announcing the availability for public review of the information described in paragraph (a) of this section and establishing a comment period of at least 60 days. During this comment period, interested persons may identify any additional information they believe the Agency should consider in the course of the registration review.

(c) *Submission of data and other information during the comment period.* The Agency may identify, either in the notice published under paragraph (b) of this section, or at any other time, data or information that it does not have but which may be useful, if available, for consideration in the registration review. Any person may submit data or information in response to such identification. In order to be considered dur-

ing a pesticide's registration review, the submitted data or information must meet the requirements listed below.

(1) In order to ensure that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information during the comment period established in the notice described in paragraph (b) of this section. The Agency may, at its discretion, consider data or information submitted at a later date.

(2) The data or information must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

(3) Submitters must clearly identify the source of any submitted data or information.

(4) Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

(d) For the purposes of this subpart, the provisions of subpart B do not apply.

### **§ 155.52 Stakeholder engagement.**

In addition to the public participation opportunities described in § 155.50 and § 155.53(c), the Agency may meet with stakeholders regarding a forthcoming or ongoing registration review. For example, before conducting a pesticide's registration review, the Agency may consult with registrants or pesticide users regarding the use and usage of the pesticide. The Agency may consult with registrants, pesticide users, or other persons during a pesticide's registration review with regard to developing risk management options for a pesticide. The Agency may informally consult with officials of Federal, State or Tribal agencies regarding a forthcoming or ongoing registration review.

(a) *Minutes of meetings with persons outside of government.* Subject to paragraph (c) of this section, if the Agency meets with one or more individuals that are not government employees to discuss matters relating to a registration review, the Agency will place in the docket a list of meeting attendees, minutes of the meeting, and any documents exchanged at the meeting, not later than the earlier of:

- (1) 45 days after the meeting; or
- (2) The date of issuance of the registration review decision.

(b) *Exchange of documents or other written material.* In the course of a meeting with a person outside of government, the Agency or that person may provide the other with a copy of a document or other written material that has not yet been released to the public. The Agency will place a copy of any such document or other written material in the docket along with the minutes of the meeting where the materials were exchanged.

(c) *Confidential business information.* The Agency will identify, but not include in the docket, any confidential business information whose disclosure is prohibited by FIFRA section 10.

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75596, Dec. 12, 2008]

**§ 155.53 Conduct of a pesticide's registration review.**

The Agency will review data and information described in § 155.50(a), (b), and (c) or submitted in response to a Data Call-In notice that it believes should be considered in the pesticide's registration review.

(a) *Assess changes since a pesticide's last review.* The Agency will assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data or information on the pesticide, including any data or information submitted

under § 155.50 or in response to a Data Call-In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under § 155.50 or in response to a Data Call-In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration.

(b) *Conduct new assessments as needed.*

(1) Active ingredient(s) in the registration review case. If the Agency finds that a new assessment of the pesticide is needed, it will determine whether it can base the new assessment on available data or information, including data or information submitted under § 155.50 or in response to a Data Call-In notice. If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(2) Individual product registrations. If the Agency finds that additional review of an individual product's registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate, to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(c) *Public participation during a pesticide's registration review.* The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the FEDERAL REGISTER announcing the